

107TH CONGRESS
1ST SESSION

H. R. 1961

To promote research to identify and evaluate the health effects of breast implants; to ensure that women receive accurate information about such implants and to encourage the Food and Drug Administration to thoroughly review the implant manufacturers' standing with the agency.

IN THE HOUSE OF REPRESENTATIVES

MAY 23, 2001

Mr. BLUNT (for himself, Mr. GREEN of Texas, Mrs. EMERSON, Ms. BROWN of Florida, Ms. KILPATRICK, Mr. ISAKSON, Mr. DAVIS of Illinois, Mr. McCRERY, Mr. OXLEY, Ms. MCCARTHY of Missouri, Mrs. MALONEY of New York, Mr. BONIOR, Mr. FILNER, Mr. BROWN of Ohio, Mr. GONZALEZ, Mr. McNULTY, Ms. JACKSON-LEE of Texas, and Ms. CARSON of Indiana) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To promote research to identify and evaluate the health effects of breast implants; to ensure that women receive accurate information about such implants and to encourage the Food and Drug Administration to thoroughly review the implant manufacturers' standing with the agency.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Breast Implant Re-
3 search and Information Act”.

4 **SEC. 2. FINDINGS AND PURPOSE.**

5 (a) FINDINGS.—Congress makes the following find-
6 ings:

7 (1) According to the Institute of Medicine, it is
8 estimated that 1,000,000 to 2,000,000 American
9 women have received breast implants over the last
10 35 years. Because there has never been a patient
11 registry for breast implant recipients it is impossible
12 to more accurately determine the number of women
13 who have received breast implants. Yet, the Amer-
14 ican Society of Plastic Surgeons estimates that in
15 1999 alone 82,975 women had breast reconstruction
16 following mastectomies and another 167,318 Amer-
17 ican women received breast implants for cosmetic
18 purposes.

19 (2) From 1985 until January 2000, FDA re-
20 ceived 127,770 adverse reaction reports for silicone
21 gel-filled breast implants and 65,720 adverse reac-
22 tion reports for saline-filled implants.

23 (3) Women need complete and accurate infor-
24 mation about the potential health risks and advan-
25 tages of breast implants so that women can make in-
26 formed decisions.

1 (4) Silicone breast implants have never been ap-
2 proved by the Food and Drug Administration; saline
3 breast implants, which consist of a saline solution
4 injected into a silicone envelope, were approved by
5 the agency in 2000 despite alarmingly high com-
6 plication and reoperation rates. After three years, 43
7 percent of the augmentation patients and 73 percent
8 of the reconstruction patients experienced local com-
9 plications and 40 percent of the reconstruction pa-
10 tients were forced to undergo additional surgery for
11 local complications and device failure.

12 (5) In 1998, the Food and Drug Administra-
13 tion opened a criminal investigation following allega-
14 tions that one of the breast implant manufacturers
15 was manipulating research data in breast implant
16 studies. When the Food and Drug Administration's
17 General and Plastic Surgery Devices Panel convened
18 in March 2000 to consider market approval for sa-
19 line implants, it was not informed of the investiga-
20 tion. Although the manufacturer's saline breast im-
21 plant was approved by the Food and Drug Adminis-
22 tration in May 2000, the investigation remains open.

23 (6) According to a 1997 Mayo Clinic study,
24 within 5 years of receiving such implants, 1 in 4
25 women required additional surgery.

1 (7) In 2000, research sponsored by the Food
2 and Drug Administration found that even among
3 women who had not sought medical treatment for
4 implant problems, almost 70 percent had at least
5 one ruptured implant after 10 to 15 years. Silicone
6 was found to be migrating away from the implants
7 in 21 percent of those women. The FDA researchers
8 concluded that “the relationship of free silicone to
9 development or progression of disease is unknown”.

10 (8) A 1993 study by Dr. Suzanne S. Teuber et
11 al., University of California, published in The Jour-
12 nal of Autoimmunity, investigated the influence of
13 silicone breast implants on the expression of
14 anticollagen antibodies and found a statistically sig-
15 nificant incidence of anticollagen antibodies in
16 women with implants. The researchers concluded
17 that silicone breast implants should not be consid-
18 ered a benign or immunologically inert material; se-
19 rious implications may result from their use.

20 (9) The Institute of Medicine’s 1999 study of
21 silicone breast implant safety found that local com-
22 plications with silicone breast implants were the pri-
23 mary safety issue, that they have not been well stud-
24 ied, and that information on these complications is
25 crucial for women deciding whether or not they want

1 breast implant surgery. Concern remains that expo-
2 sure to silicone breast implants may result in cur-
3 rently undefined connective tissue or autoimmune
4 diseases.

5 (10) A 2001 National Cancer Institute study
6 found breast implant recipients suffer from higher
7 rates of lung and brain cancer than other plastic
8 surgery patients.

9 (11) A 1999 case report by Dr. Suzanne S.
10 Teuber et al., University of California, published in
11 The Journal of Rheumatology, found evidence of sili-
12 cone migration in women with ruptured or leaking
13 silicone breast implants. These patients experienced
14 severe local inflammation and complications result-
15 ing from silicone migration to the axilla, arm or ab-
16 dominal wall. Researchers concluded that once sili-
17 cone gel leaves the implant, it is not biologically
18 inert and in some persons can elicit profound
19 pathologic responses.

20 (12) According to many reports, including a
21 study published in the Journal of the National Can-
22 cer Institute, the presence of a silicone breast im-
23 plant may create difficulties in obtaining accurate
24 and thorough mammograms because as much as 40
25 percent of the breast tissue can be masked by the

1 implant. This delays the early detection of breast
2 cancer in women.

3 (13) According to a 2000 Food and Drug Ad-
4 ministration publication, women of childbearing age
5 who want to breast feed should be aware of the neg-
6 ative impact of breast implants on breast feeding. It
7 is not known if a small amount of silicone may pass
8 from the silicone shell of an implant into breast
9 milk. If this occurs, it is not known what effect it
10 may have on the nursing infant.

11 (b) PURPOSE.—It is the purpose of this Act to pro-
12 mote research to identify and evaluate the health effects
13 of breast implants, to ensure that women receive accurate
14 information about such implants and to encourage the
15 Food and Drug Administration to conclude its criminal
16 investigation based on the allegations of wrong-doing by
17 one of the implant manufacturers which ultimately may
18 affect their products and the health of American women.

19 (c) RULE OF CONSTRUCTION.—Nothing in this Act
20 shall be construed to affect any rule or regulation promul-
21 gated under the authority of the Federal Food, Drug and
22 Cosmetic Act (21 U.S. 301 et seq.) that is in effect on
23 the date of enactment of this Act relating to the avail-
24 ability of silicone breast implant for reconstruction after
25 mastectomy, correction of congenital deformities, or re-

1 placement for ruptured silicone implants for augmenta-
2 tion.

3 **SEC. 3. EXPANSION AND INTENSIFICATION OF ACTIVITIES**
4 **REGARDING SILICONE BREAST IMPLANTS AT**
5 **THE NATIONAL INSTITUTES OF HEALTH.**

6 (a) STATUS OF EXISTING RESEARCH.—The Director
7 of the National Institutes of Health shall report to all ap-
8 propriate committees of Congress on the status of the ex-
9 isting breast implant research funded by such Institutes
10 within 90 days after the date of the enactment of this Act.

11 (b) AMENDMENT TO PUBLIC HEALTH SERVICE
12 ACT.—Part H of title IV of the Public Health Service Act
13 (42 U.S.C. 289 et seq.) is amended by adding at the end
14 of the following:

15 **“SEC. 498C. BREAST IMPLANT RESEARCH.**

16 “(a) INSTITUTE-WIDE COORDINATOR.—The Director
17 of NIH shall appoint an appropriate official of the Depart-
18 ment of Health and Human Services to serve as the Na-
19 tional Institutes of Health coordinator regarding breast
20 implant research. Such coordinator shall encourage and
21 coordinate the participation of all appropriate Institutes
22 research including—

23 “(1) the Office of Research on Women’s
24 Health;

1 “(2) the National Institute of Allergy and In-
2 fectious Diseases;

3 “(3) the National Institute of Arthritis and
4 Musculoskeletal and Skin diseases;

5 “(4) the National Institute of Child Health and
6 Human Development;

7 “(5) the National Institute of Environmental
8 Health Sciences;

9 “(6) the National Institute of Neurological Dis-
10 orders and Stroke; and

11 “(7) the National Cancer Institute.

12 “(b) STUDY SECTIONS.—The Director of NIH shall
13 establish a study section or special emphasis panel if de-
14 termined to be appropriate, for the National Institutes of
15 Health to review extramural research grant applications
16 regarding breast implants to ensure the appropriate de-
17 sign and high quality of such research and shall take ap-
18 propriate action to ensure the quality of intramural re-
19 search activities.

20 “(c) CLINICAL STUDY.—

21 “(1) IN GENERAL.—The Director of NIH shall
22 conduct or support research to expand the under-
23 standing of the health implications of both saline
24 and silicone breast implants. Such research should,
25 if determined to be scientifically appropriate, include

1 multidisciplinary, clinical, case-controlled study of
2 women with breast implants for at least eight years
3 whether it be one prosthesis or multiple, and dif-
4 ferentiate between women receiving implants for
5 mastectomy, reconstructive or cosmetic purposes and
6 include subsets of women with saline implants and
7 silicone implants. Such a study should focus on the
8 rate of local complications which includes capsular
9 contracture, leakage, loss of nipple sensation, defla-
10 tion and rupture as well as the presentation of atypi-
11 cal symptoms, silicone migration, neurological dys-
12 function, and immune system irregularities, and
13 evaluate to what extent if any, their health differs
14 from that of suitable controls.

15 “(2) ANNUAL REPORT.—The Director of NIH
16 shall annually prepare and submit to the appropriate
17 Committees of Congress a report concerning the re-
18 sults of the study conducted under paragraph (1).”.

19 **SEC. 4. INTENSIFICATION OF ACTIVITIES REGARDING**
20 **POSTMARKET RESEARCH OF SALINE BREAST**
21 **IMPLANTS AT THE FOOD AND DRUG ADMINIS-**
22 **TRATION.**

23 To ensure that the Food and Drug Administration
24 conducts postmarket evaluations of saline implant manu-
25 facturers’ data based on the postmarket recommendations

1 made by the Food and Drug Administration's General and
2 Plastic Surgery Devices Panel, the Commissioner of Food
3 and Drugs shall report to Congress on the implementation
4 status of the postmarket recommendations at 6, 12, and
5 18 month intervals after the date of the enactment of this
6 Act and annually thereafter.

7 **SEC. 5. EXPANSION AND INTENSIFICATION OF ACTIVITIES**
8 **REGARDING SILICONE BREAST IMPLANTS AT**
9 **THE FOOD AND DRUG ADMINISTRATION.**

10 To assist women in receiving accurate and complete
11 information about the risks of silicone breast implants, the
12 Commissioner of Food and Drugs shall—

13 (1) expedite the conclusion of the agency's
14 criminal investigation into allegations of wrong-doing
15 by one of the implant manufacturers; brief appro-
16 priate Committees of Congress on the findings and
17 take appropriate action within 90 days after the
18 date of the enactment of this Act;

19 (2) ensure that the toll-free consumer informa-
20 tion line and materials concerning breast implants
21 provided by the Food and Drug Administration are
22 available, up to date, and responsive to reports of
23 problems with breast implants, and that timely ag-
24 gregate data concerning such reports shall be made

1 available to the public upon request and consistent
2 with existing confidentiality standards;

3 (3) require that manufacturers of silicone
4 breast implants update implant package inserts and
5 informed consent documents regularly to reflect ac-
6 curate information about such implants, particularly
7 the rate of local complications and ruptures of such
8 implants;

9 (4) require that any manufacturers of such im-
10 plants that are conducting clinical studies on silicone
11 breast implants—

12 (A) require its clinical investigators to pro-
13 vide prospective patients with the Food and
14 Drug Administration’s breast implant booklet;

15 (B) amend such study protocol and in-
16 formed consent document to reflect that pa-
17 tients must be provided with a copy of informed
18 consent documents at the initial, or earliest pos-
19 sible, consultation regarding breast prosthesis;

20 (C) amend the informed consent protocol
21 to inform women about how to obtain a
22 Medwatch form and encourage any woman who
23 withdraws from the study, or who would like to
24 report such problem or concerns with the study
25 and reason for withdrawing; and

1 (D) amend the informed consent document
2 to provide potential participants with the inclu-
3 sion criteria for the clinical trial and the toll-
4 free Consumer Information number; and
5 (5) appoint a special ad hoc patient information
6 panel that—

7 (A) convenes annually for the sole purpose
8 of reviewing breast implant information and ad-
9 vertisements provided by the manufacturers and
10 the Food and Drug Administration to ensure
11 consumer information is thorough and accurate;
12 and

13 (B) includes in its membership (but is not
14 limited to) saline and silicone breast implant re-
15 cipients, bioethicists, rheumatologists, and
16 oncologists with experience in both clinical care
17 and research regarding breast implants.

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